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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

THE LARYNGEAL MASK COMPANY
LTD. and LMA NORTH AMERICA,
INC.,

Plaintiffs,

v.

AMBU A/S, AMBU INC., AMBU LTD.,
and AMBU SDN. BHD.,

Defendants.

AMBU A/S, AMBU INC., AMBU LTD.,
and AMBU SDN. BHD.,

Counterclaimants,

v.

THE LARYNGEAL MASK COMPANY
LTD. and LMA NORTH AMERICA,
INC.,

Counter-Defendants.

Case No. 3:07-cv-01988-DMS-NLS

**DEFENDANTS AMBU A/S, AMBU INC.,
AMBU LTD., AND AMBU SDN. BHD.'S
REPLY IN SUPPORT OF THEIR MOTION
FOR LEAVE TO AMEND ANSWER AND
COUNTERCLAIMS**

**Judge: Honorable Dana M. Sabraw
Date: August 22, 2008
Time: 1:30 p.m.
Courtroom: 10**

I. INTRODUCTION

Counterclaimants Ambu A/S, Ambu Inc., Ambu Ltd., and Ambu Sdn. Bhd. (collectively “Ambu”) respectfully submits this reply to Counterdefendants The Laryngeal Mask Company Ltd. and LMA North America, Inc.’s Opposition to Defendants’ Motion for Leave to Amend Answer and Counterclaims. LMA has failed to meet its burden of establishing a basis for denial of this motion. First, Ambu’s counterclaims are timely, being proffered prior to the deadline for amending pleadings set by the court, and being triggered by a very recent change of circumstances, as LMA has returned to an unlawful and unfair marketing practice that Ambu had understood it to have abandoned. Second, given the early stage this action is in, with the first exchange of documents still ongoing, no depositions having yet been taken, and the fact discovery cutoff and trial are more than ninth months and sixteen months away, respectively, there will be no prejudice to LMA if Ambu’s counterclaims are included. Third, given the fact that the claims and counterclaims related to the same products, and given the extensive overlap in discovery on both sets of claims, permitting amendment in this case will serve judicial economy. Ultimately, only one jury should be required to learn about the competing laryngeal mask products at issue and their marketing.

II. ARGUMENT**A. Federal Rule of Civil Procedure 15 Governs.**

LMA incorrectly contends that Ambu’s proposed counterclaims are “tardy” by wrongfully asserting that Rule 13(f) of the Federal Rules of Civil Procedure governs Ambu’s motion. Pl.’s Opposition to Defs.’ Mot. for Leave to Amend Ans. and Counterclaims, 5-6 (Aug. 8, 2008) (hereinafter “Pl.’s Opp.”). Ambu did not omit its proposed counterclaims due to neglect or oversight. Rather, they are based on a change in circumstances. Accordingly, the appropriate rule that governs is Rule 15 of the Federal Rules of Civil Procedure, which provides that the Court shall grant leave to amend pleadings freely when justice so requires.

Moreover, even if Rule 13 applied, it still freely permits amendment where justice requires. Fed. R Civ. P. 13(f); *Ralston-Purina Co. v. Bertie*, 541 F.2d 1363, 1367 (9th Cir. 1976) (Rule 13(f)’s provision that allows a party to obtain leave to assert a counterclaim when,

1 *inter alia*, justice requires “is generally applied liberally”). Here, Ambu believed that LMA had
 2 discontinued the marketing campaign at issue. Once it obtained reports from the field to the
 3 contrary, it promptly sought leave to amend. Under these circumstances, denial of leave to
 4 amend would be inappropriate under either Rule 13 or Rule 15.

5 **B. LMA Will Not Be Prejudiced by Ambu’s Amended Pleading.**

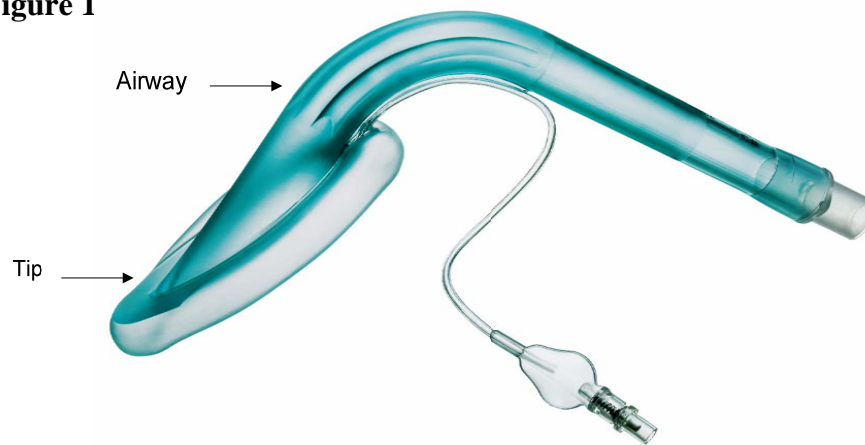
6 In order to defeat this motion, LMA had the burden of showing cognizable prejudice. *See*
 7 *DCD Programs, Ltd. v. Leighton*, 833 F.2d 183, 187 (9th Cir. 1987) (noting that the party
 8 opposing amendment “bears the burden of showing prejudice”). It has failed to meet that burden
 9 as, contrary to LMA’s arguments, Ambu’s proposed counterclaims are related to the current
 10 action and would not delay its resolution.

11 **1. Ambu’s Proposed Counterclaims are Related to the Current Action**

12 **a. *The Patent-at-Issue Claims an Entire Laryngeal Mask Assembly***

13 LMA incorrectly contends that the product features at issue in the patent case are
 14 insufficiently related to those at issue in the proposed counterclaims. LMA tries to argue that
 15 although the same products are at issue with regard to both sets of claims, the patent infringement
 16 claims are insufficiently related to the unfair competition claims because one concerns “Ambu’s
 17 use of a ‘reinforced tip,’” and one relates to the “shape and the rigidity of its tube.” Pl.’s Opp. at
 18 4-5. However, as Figure 1 below depicts, the “reinforced tip” and the “pre-curved shape” of the
 19 tube are two parts of the same product.

20 **Figure 1**



1 Accordingly, LMA's contention that one jury should learn about the front end of the Ambu
2 devices and another jury should learn about their midsection should be rejected. Judicial
3 economy would be served by a single exploration of the market for laryngeal masks.

4 Moreover, LMA's argument about relatedness is based on a description of its patent claim
5 that is misleading. The patent-at-issue, U.S. Patent No. 7,156,100 (the "'100 patent") claims an
6 entire laryngeal mask assembly, not merely a mask's reinforced tip. Pl.'s Opp. Ex. 3. Claim 1 of
7 the '100 patent claims, "A laryngeal-mask airway device," and then recites a number of features
8 including a backplate, an inflatable cuff, etc. One of the features claimed is "... an airway
9 extending from a laryngeal inlet of the patient, through the central opening" in the cuff. It is
10 black letter law that in order to prove its infringement claim, LMA must prove the presence of
11 each and every one of these claimed features. *Cole v. Kimberly-Clark Corp.*, 102 F.3d 524, 532
12 (Fed. Cir. 1996). Laryngeal mask airway tubes are thus already at issue in this case, as LMA
13 must adduce evidence on Ambu's airways.

14 In addition, LMA contends that Ambu added a reinforced tip to its products in order to
15 avoid foldover of the mask during insertion. Accordingly, for the purposes of the patent claims,
16 there will be evidence submitted on the behavior of the masks on insertion. This overlaps with
17 the evidence relevant to Ambu's counterclaims. The brochure that LMA has published, which is
18 at the center of Ambu's counterclaims (the "LMA Brochure"), rests on assertions of how the
19 Ambu products perform during insertion. Pl.'s Opp. Ex. 4 at 5, 7, 9.

20 Accordingly, LMA's claim of prejudice should be rejected. *See SAES Getters, S.p.A. v.*
21 *Aeronex, Inc.*, 219 F. Supp. 2d 1081, 1086 (S.D. Cal. 2002) (substantial prejudice only exists
22 where the amendments would significantly alter the nature of the litigation). Ambu's
23 counterclaims related to the same product lines and the relevant evidence will overlap with what
24 is relevant on the patent claims.

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b. *The Discovery Sought for the Patent Infringement Claim Overlaps with the Discovery required for Ambu's Proposed Counterclaims.*

LMA has asserted that on its patent claims, it is entitled to either lost profits or a reasonable royalty. Declaration of Dennis M. Faigal in Support of Defendants Ambu A/S, Ambu Inc., Ambu Ltd., and Ambu Sdn. Bhd.'s Reply in Support of Their Motion for Leave to Amend Answer and Counterclaims ("Faigal Decl.") ¶ 2, Ex. A. To that end, LMA served discovery requests to Ambu for documents that identify Ambu's customers,¹ documents that describe customers' decision-making on whether to purchase Ambu's products,² and documents that relate to Ambu's efforts to compete against LMA's products.³ Given how broadly LMA is already seeking discovery, it is difficult to envision how addition of Ambu's counterclaims "would substantially prejudice LMA by requiring additional and extensive discovery" that LMA is not already seeking. Pl.'s Opp. at 9.

Further, LMA's argument that it will be prejudiced by requiring "many more depositions of customers and sales staffs . . . regarding the allegedly false statements" cannot be sustained. *Id.* As a preliminary matter, not a single deposition has been scheduled and there is more than ample time for LMA to depose whatever witnesses it requires. *See infra* Sec. III.B.2. Furthermore, in the Joint Report of FRCP Rule 26(f) Conference of Counsel and Proposed Discovery Plan, LMA took the unusual position in the patent case that it intends to "conduct third party discovery with respect to damages issues" including "*at least* six Group Purchasing Organizations . . . in the United States through which most hospitals negotiate and purchase the parties' competing products, not to mention the numerous doctors and hospital administrators involved in purchasing decisions." Dkt. No. 53 at 4:6-19. This type of witness would also know about LMA's illegal sales and marketing tactics. Accordingly, LMA should not now get away

¹ Plaintiff's Request for Production No. 69 requests "[d]ocuments sufficient to identify all customers of each different Accused Product in the United States." Faigal Decl. ¶ 5, Ex. C.

² Plaintiff's Request for Production No. 46 requests "documents that discuss, describe or analyze the reasons why or whether Your customers have purchased or have not purchased Your Accused Products." Faigal Decl. ¶ 5, Ex. C.

³ Plaintiff's Request for Production No. 44 requests "documents relating to Your efforts to compete against another supplier's laryngeal mask airway devices." Faigal Decl. ¶ 5, Ex. C.

1 with arguing that it would be prejudiced by requiring this type of discovery.

2 In addition, in their Rule 26(a)(1) Initial Disclosures, LMA identified its sales directors
3 and Ambu identified a general manager responsible for sales and marketing as potential witnesses
4 at trial. Faigal Decl. ¶¶ 2, 4; Exs. A, B. Since the parties have already indentified these
5 individuals as witnesses, LMA simply has no basis to argue that it will be burdened by requiring
6 depositions of many more “sales staffs.”

7 **2. Ambu’s Proposed Counterclaims Will Not Unduly Delay the Resolution**
8 **of this Case.**

9 LMA similarly will not be prejudiced if the case proceeds on its current schedule.
10 Currently, nine months still remain before fact discovery closes. As noted above, witnesses
11 relevant to both sets of claims have already been identified and documents relevant to both sets of
12 claims requested. Moreover, trial is not scheduled to begin until December 2009. This provides
13 more than ample time for LMA to mount its defense to the proposed counterclaims. *See Santana*
14 *Row Hotel Partners v. Zurich Am. Ins. Co.*, 2006 U.S. Dist. LEXIS 67509 at *7 (N.D. Cal. June
15 20, 2006) (holding that undue prejudice does not exist where “[a]mple time remains for
16 Defendants to carry out whatever discovery or other preparation is necessary to respond to the new
17 allegations”); *see also Switchmusic.com, Inc., v. U.S. Music Corp.*, No. CV 04-4588RGKPLAX,
18 2005 WL 3750748 (C.D. Cal. Dec. 12, 2005) (the court held that granting the defendant’s motion
19 for leave to amend would prejudice the plaintiff because fact discovery had already closed and
20 because of the “impending trial date,” facts which are different than in the instant case where fact
21 discovery is still open and trial is more than one year away).

22 **C. Ambu Did Not Unduly Delay in Seeking to Amend its Pleading.**

23 **1. Ambu Did Not Know LMA’s Wrongful Sales and Marketing Conduct**
24 **Had Not Abated.**

25 LMA argues that to preserve its unfair competition claims, Ambu should have sued on
26 them months ago, despite the fact that at the time Ambu believed that those deceptive sales and
27 marketing tactics had been discontinued. Ambu should not be punished for exercising restraint in
28 its initial pleadings in this case. As Mr. Wendler, an Ambu Executive Vice President, explained in
his declaration, Ambu believed that the worst of LMA’s marketing tactics had changed. Decl. of

1 Henrik Wendler in Support of Defs. Ambu A/S, Ambu Inc., Ambu Ltd., and Ambu Sdn. Bhd.'s
2 Mot. for Leave to Amend Ans. and Counterclaims (Dkt. No. 63). Only ten days ago, however,
3 Ambu learned that that was not the case, and it has acted promptly to add those claims before the
4 court deadline. The fact that LMA may have in fact in the interim quietly continued its deceptive
5 campaign without Ambu's knowledge does not mean Ambu delayed in bringing its claim.

6 Nor should the Court give any credence to LMA's objection to the Court's consideration
7 of Mr. Wendler's declaration. LMA's argument that all evidence of Ambu's knowledge should
8 have been provided in a form admissible at trial (Pl.'s Opp. at 8) is without citation for a reason.
9 The standards for submission of evidence even at the summary judgment stage, much less on a
10 motion for leave to amend a pleading, are not the same as the standards applied at trial. *Fraser*
11 *v. Goodale*, 342 F.3d 1032, 1036 (9th Cir. 2003). In other words, even at the summary judgment
12 phase, evidence must be merely of the type that can be reduced to admissible evidence.

13 *Interstate Commer. Bldg. Servs. v. Bank of Am. Nat'l Trust and Sav. Ass'n*, 23 F. Supp. 2d 1166,
14 1176 (D. Nev. 1998). There can be no doubt that Ambu representatives will be available to
15 testify live at trial about the specific accounts affected by LMA's misconduct.

16 In sum, given that Ambu was unaware of LMA's continued misconduct, Ambu did not
17 unduly delay in seeking to file additional false advertising and unfair competition counterclaims
18 only ten days after learning of LMA's most recent activities.

19 **2. Each Occurrence of LMA's False Advertising is Separately Actionable.**

20 LMA also argues that because Ambu's claims are based on conduct similar to that
21 engaged in by LMA several years ago, those claims are somehow stale. That is simply not the
22 law. Each instance of false advertising to each customer or prospective customer is a tort, and a
23 tort that is separately actionable. *Suh v. Yang*, 987 F. Supp. 783, 795-796 (N.D. Cal. 1997).
24 Thus, in the *Suh* case the court held that the statute of limitations had not accrued because the
25 defendant's acts of displaying an allegedly infringing service name on its products and
26 advertisements were deemed a series of multiple wrongs as opposed to a single wrong because
27 each instance could create a separate cause of action, some of which occurred within the statute of
28 limitations period. Similarly, here, the court should reject LMA's staleness argument in the

context of this motion to amend because each new instance of unfair competition represents a new wrong that gives rise to a separate cause of action. LMA engaged in a separate wrongful act each time it distributed the LMA Brochure to a customer, each time a LMA sales representative falsely claimed to a customer that Ambu's product causes nerve damage, and each time LMA falsely reported that certain institutional customers switched from Ambu to LMA.

Given these facts, and the applicable law on unfair competition claims, the cases that LMA cited regarding "new facts" are inapplicable. Pl.'s Opp. at 7. For example, in *Edwards Lifesciences LLC v. Cook Inc.*, the court refused to permit a party to add a defense of inequitable conduct. No. C 03-03817 JSW, 2008 WL 913328, at *3 (N.D. Cal. Apr. 2, 2008).⁴ Inequitable conduct occurs when a patent holder intentionally withholds information from the Patent Office during prosecution of a patent. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1374 (Fed. Cir. 2008). The relevant facts thus occur well prior to any lawsuit being initiated, and do not change over time. In contrast, here, the marketing of a product is an ongoing activity, and new events occur each day. Here, Ambu learned of altogether new acts of misconduct.

D. Ambu's Amended Counterclaims are not Futile.

An amendment may be denied for futility only if no set of facts can be proved under the amendment which would constitute a valid claim. *See Miller v. Rykiff-Sexton, Inc.*, 845 F.2d 209, 214 (9th Cir. 1988); *see also SAES Getters*, 219 F. Supp. 2d at 1086 ("an amendment is 'futile' only if it would clearly be subject to dismissal"). LMA contends that its Brochure cannot be false because a known risk of nerve damage is disclosed in Ambu's instructions for use. Pl.'s Opp. at 12. However, LMA's brochure goes well beyond citing this known risk of laryngeal mask products.

Rather, as Ambu's proposed counterclaims allege, the LMA Brochure is itself false and misleading in that its overall message is that the LMA product is safer and thus superior to

⁴ *Edwards Lifesciences LLC* is further distinguished because the movant attempted to add the inequitable conduct defense after depositions had been taken on the relevant facts and discovery had closed. In contrast, here, discovery is still open and no depositions have even been scheduled, much less taken.

1 Ambu's competitive product because the use of Ambu's product creates a greater risk of nerve
2 damage to patients than does LMA's. Memorandum of Points and Authorities In Support of
3 Defendants' Motion for Leave to Amend Answer and Counterclaims, Ex. A (Dkt. No. 63).
4 Specifically, the LMA Brochure relies on the unreliable Ferson Study to falsely purport that
5 Ambu's product sits higher when inserted in a patient which causes it to press against the hyoid
6 bone thereby causing nerve damage. Not only did LMA publish the false Brochure, its sales
7 representative repeated similar assertions when selling against Ambu.

8 This conduct is particularly disturbing given the fact that LMA has disclosed that its own
9 products carry similar risks, risks that are supported by publications detailing the adverse
10 consequences of LMA's design. Faigal Decl. ¶¶ 6, 7; Exs. D, E. In its marketing materials, LMA
11 attributes this risk of its own products to user error, noting hypoglossal nerve injury resulting
12 from "malposition or excessive intracuff pressure." Faigal Decl. ¶ 6, Ex. D. Yet in its Brochure,
13 LMA attributes Ambu's risk to Ambu's design. LMA's Brochure identifies a unique feature, the
14 rigid and pre-curved tube, of Ambu's product to deceive readers into believing that LMA's
15 product is safer than Ambu's. Pl.'s Opp. Ex. 4. Further, LMA bases these assertions on the
16 inadequate and inapplicable data provided by the Ferson Study, which by itself is false and
17 misleading. This conduct goes well beyond referring to known risks, and clearly adequate to
18 support a valid claim of false advertising according to the standard set forth in *Miller v. Rykiff-*
19 *Sexton, Inc.*

20 **III. CONCLUSION**

21 For the foregoing reasons, Ambu respectfully requests that this Court grant its motion for
22 leave to file its Amended Answer and Counterclaims.

23 Dated: August 15, 2008

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who are deemed to have consented to electronic service are being served with a copy of this document via the Court's CM/ECF system per Local Rule 5.2 on August 15, 2008.

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